

REMARKS

By the above amendment, claim 25 is canceled and replaced with new claim 36 and claims dependent on claim 25 are revised to be dependent on claim 36. Currently, claims 26-36 are before the Examiner with claims 13-17 withdrawn from consideration.

First, the Examiner is again requested to respond to Applicants request that the IDS be acknowledged since English abstracts were supplied with the IDS.

In the outstanding Office Action, the Examiner rejected claim 25 under 35 USC §112, first paragraph, on the grounds that it was not supported by the specification. In response to this rejection, claim 25 is replaced with new claim 36. Applicants submit that new claim 36 is supported by the specification so that the rejection based on 35 USC §112, first paragraph should be withdrawn.

Turning now to the prior art rejection, Applicants submit that the Examiner has committed error in alleging that the effects of the invention are expected so that Applicants cannot rebut the allegation that it would be obvious to use CMC as a stabilizing agent.

In review, the Examiner uses D3 as the primary reference and combines it with D1 to teach CMC as a stabilizer. The Examiner concludes that it would be obvious to use the CMC stabilizer of D1 in D3, thus resulting in the invention. The Examiner considers the improvements to the stability of the colloidal particles in the context of nebulization to be expected.

D1 has a large number of surface stabilizers including non-ionic, anionic, and cationic surfactants. There is no disclosure in D1 of the special effects that CMC would

impart in the context of the invention; CMC is just one of a myriad of stabilizers disclosed in D1.

What Applicants are arguing is that the use of CMC as a stabilizer for the claimed comb polymer produces unexpected results in terms of high stability of the particles when nebulized. As explained in paragraph [0094], the particles of the invention are characterized by uncommonly high stability and, because of this, the particles are particularly suitable for pulmonary applications.

Paragraphs [0090-0094] of Applicants' published application detail the comparison in the specification between the invention using CMC-comprising colloidal particles and the colloidal RG 503 particles without CMC. This comparison reveals that colloidal RG 503 particles agglomerate whereas the particles of the invention remain stable. This result is not predictable from the teachings of D1, which says nothing about the effect of CMC when colloidal particles are nebulized. It is error for the Examiner to consider the comparison in the specification as nothing more than showing an expected result based on the teachings of D1. In fact, Applicants have demonstrated an unexpected result in the context of nebulizing colloidal particles and this result is a rebuttal of the allegation of obviousness. Therefore, claim 36 and its dependent claims are patentable over the applied prior art.

Applicants also contend that since claim 36 is patentable, the restriction requirement should be withdrawn so that the method of use claims are allowed along with the product claims. Applicants also note that the claim dependency needs to be corrected for claims 13-17 and, if the withdrawn claims are rejoined as part of an allowance of this application, the Examiner could make the changes to these claims by Examiner's amendment.

Accordingly, the Examiner is requested to examine this application in light of this response and pass all pending claims onto issuance.

If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

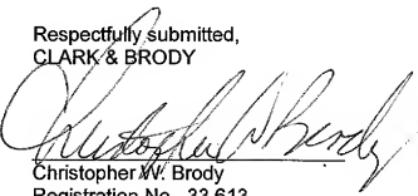
The above constitutes a complete response to all issues raised in the outstanding Office Action.

Again, reconsideration and allowance of this application is respectfully requested.

Applicants petition for a two month extension of time.

Please charge the extension of time fee (\$245) and any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,
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